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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte DANIELA BUSSE, HEIKE CONRAD, and HANNS HATT¹

Appeal 2019-005967 Application 15/310,195 Technology Center 1600

Before ERIC B. GRIMES, RICHARD M. LEBOVITZ, and JEFFREY N. FREDMAN, *Administrative Patent Judges*.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to a method for acceleration of wound healing, which have been rejected as obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM-IN-PART.

STATEMENT OF THE CASE

"The invention relates to a drug containing derivatives of the formula (I)... for acceleration of wound healing." Spec. ¶ 12. "The derivatives of

¹ Appellant identifies the real party in interest as SYMRISE AG. Appeal Br. 1. We use the word Appellant to refer to "applicant" as defined in 37 C.F.R. § 1.42(a).

the formula (I) are preferably odorants with a sandalwood odor such as Sandalore® (R1 = methyl) or Brahmanol® (R1 = hydrogen)." Spec. ¶ 13. "[T]he administration of Sandalore® and/or Brahmanol®, preferably by topical application to the skin, causes acceleration of wound healing, primarily by activation of the receptor OR2AT4 and the cell proliferation and migration caused thereby." Spec. ¶ 18.

Claims 4–7 and 12–16 are on appeal. Claims 4 and 12, reproduced below, are illustrative:

Claim 4: A method for acceleration of wound healing, comprising accelerating the healing of a wound by applying an effective amount of a drug containing a derivative of the formula (I)

in which R^1 denotes hydrogen or methyl to activate the olfactory receptor OR2AT4.

Claim 12: A method for acceleration of wound healing, comprising accelerating the healing of a wound that results from the opening of tissue from the epidermis resulting in a need for tissue closure via tissue regeneration by applying to the wound that results from the opening of tissue, an amount of a drug containing a derivative of formula (I)

in which R¹ denotes hydrogen or methyl, effective to accelerate tissue regeneration at the wound site, and wherein the drug activates the olfactory receptor OR2AT4, increases the proliferation and migration of HaCaT cells and regenerates cells at the wound site at a rate increased by the application of the drug to the wound.

OPINION

Obviousness

Claims 4–7 and 12–16 stand rejected under 35 U.S.C. § 103 as being obvious based on Burger² and Elson³ (Final Action⁴ 10).⁵

The Examiner finds that "Burger teaches that retinol (vitamin A) is an endogenous compound well known for essential <u>epithelial cell</u> <u>differentiation</u> and ha[s] been used in . . . skin care and skin repair (wound healing requires skin repair)." Final Action 10. The Examiner finds that Burger discloses preferred compounds, including Brahmanol®, "that may prevent degradation of retinol." Final Action 10–11. The Examiner also finds that Burger teaches "a composition comprising Brahmanol for use in skin care such as photodamaged skin (by repairing skin) etc by proliferation of cells . . . (i.e. cell regenerating effect)." Final Action 11. The Examiner finds that Burger is "silent about wound healing." Final Action 12.

² Burger, US 5,759,556, June 2, 1998.

³ Melvin L. Elson, *The Role of Retinoids in Wound Healing*, J. Amer. Acad. Dermatol. 39:S79–S81 (1998).

⁴ Office Action mailed Feb. 21, 2019.

⁵ The Examiner separately rejected claims 4–7, 12, 13, and 15 (Ans. 4); however, both rejections are based on Burger and Elson, and are substantively the same. The separate rejection of claims 4–7, 12, 13, and 15 thus is cumulative of the rejection of claims 4–7 and 12–16.

The Examiner finds that "Elson teaches use of retinol in **enhanced wound healing (i.e. accelerated wound healing)** . . . and Burger teaches retinol in skin repair and adding compounds such as Brahmanol to increase the stability of retinol and using the composition in repairing skin damage." Final Action 14. The Examiner concludes that "it would have been *prima facie* obvious to a person of ordinary skill in the art that a composition comprising retinol and brahmanol may be useful in accelerating wound healing as Elson teaches use of retinol in enhanced wound healing and Burger teaches a composition with compound of the instant claims in increasing the stability of retinol and using the composition in repairing skin damage." *Id*.

Appellant states that "the ordinary meeting [sic] of the specific claim language, the specification and the prosecution history all confirm that the claims are directed to methods of closing an opening in the skin, such opening resulting in the need for tissue closure via tissue regeneration. Wound healing is distinct from methods of treating wrinkles, dark spots and rashes." Appeal Br. 7.

Appellant argues that "Elson does not describe applying retinol to a wound, but actually pretreating closed skin with tretinoin not retinol." Appeal Br. 10. Appellant states that "tretinoin is not retinol. Tretinoin is an acid, also known as all-trans retinoic acid." Appeal Br. 15. Appellant argues that, "while Burger discusses stabilizing retinol with Brahmanol, neither Burger nor Elson describe stabilizing tretinoin with Brahmanol. Therefore, the cited art does <u>not</u> indicate that tretinoin is necessarily or ever combined with brahmanol to stabilize the tretinoin. Accordingly, there is no

evidence in the record that tretinoin treatments inherently include stabilizing amounts of Brahmanol." *Id*.

We agree with the Examiner, however, that the methods of claims 4 and 12 would have been obvious to a person of ordinary skill in the art based on Burger in view of Elson. Burger states that "the use of retinol or esters of retinol would be preferred over retinoic acid. . . . Retinol is also considered much safer than retinoic acid." Burger 1:27–31. Burger also states that "although retinol and retinyl esters are safer to use than retinoic acid, they are less effective than retinoic acid at providing skin benefits." *Id.* at 1:53–55. Burger discloses that certain cyclic hydrocarbons "potentiate the action of retinol by increasing the amount of retinol available for conversion to retinoic acid. Thus, a mixture of selected cyclic hydrocarbons with retinol or retinyl esters mimics retinoic acid yet is safer to use than retinoic acid." *Id.* at 1:59–63. Suitable cyclic compounds include Brahmanol. *Id.* at 3:43–44, 4:55–60.

Elson explains that "[e]arly wound healing studies that used topical retinoids in animals demonstrated enhanced healing of full-thickness skin wounds." Elson S79. Elson discloses that "[p]retreatment with a retinoid before dermabrasion, a chemical peel, or laser resurfacing can facilitate an accelerated healing process after the surgical event." *Id.* at S79–S80. Elson states that "the application of tretinoin before dermatologic procedures accelerated wound healing." *Id.* at S80. Tretinoin is a form of retinoic acid. *See* Appeal Br. 15.

In sum, Burger teaches that the combination of retinol with certain cyclic hydrocarbons such as Brahmanol® results in a product that

potentiates the action of retinol and mimics retinoic acid (i.e., tretinoin) with the advantage that it is safer to use than retinoic acid. Elson teaches that the application of tretinoin (i.e., retinoic acid) before dermatologic procedures accelerated wound healing.

"Motivation to combine is a factual determination as to whether there is a known reason a skilled artisan would have been motivated to combine elements to arrive at a claimed combination." *Arctic Cat, Inc. v. Bombardier Recreational Prods., Inc.*, 876 F.3d 1350, 1359 (Fed. Cir. 2017). Here, a skilled artisan would have considered it obvious to replace Elson's tretinoin (retinoic acid) with the combination of Brahmanol® and retinol disclosed by Burger, because Burger teaches that such a combination "mimics retinoic acid yet is safer to use than retinoic acid." Burger 1:61–63.

Appellant argues that "[i]ndependent Claim 4 literally describes the acceleration of wound healing that involves the activation of olfactory receptor OR2AT4. Independent Claim 12 literally describes accelerating the healing of a wound that results from the opening of tissue from the epidermis, resulting in a need for tissue closure via tissue regeneration." Appeal Br. 7. Appellant argues that "the claims are directed to methods of closing an opening in the skin, such opening resulting in the need for tissue closure via tissue regeneration. Wound healing is distinct from methods of treating wrinkles, dark spots and rashes." *Id*.

"[T]he claims define the invention. . . . [L]imitations from the specification are not to be read into the claims." *Sjolund v. Musland*, 847 F.2d 1573, 1582 (Fed. Cir. 1988). Since claim 4 does not recite application of a drug to a wound, it does not preclude pretreatment before a cosmetic

surgery procedure, as taught by Elson. As indicated above, Elson discloses that "the application of tretinoin before dermatologic procedures accelerated wound healing." Elson S80. Thus, regarding claim 4, a skilled artisan would have considered it obvious to apply an effective amount of a combination of retinol and Brahmanol®, as taught by Burger, in order to accelerate the healing of a wound, as taught by Elson.

Regarding claim 12, also as indicated above, Elson explains that "[e]arly wound healing studies that used topical retinoids in animals demonstrated enhanced healing of full-thickness skin wounds." Elson S79. Thus, regarding claim 12, a skilled artisan would have considered it obvious to topically apply an amount of Brahmanol® combined with retinol, as taught by Burger, effective to enhance healing at the wound site, as taught by Elson.

Appellant also argues that "[c]laims 13 and 16 employ the 'consisting essentially of' preamble, which excludes ingredients having a material effect on the basic and novel characteristics of the invention. Therefore, claims 13 and 16 exclude methods employing material amounts of e.g., retinol, to have any effect on receptor activation and skin closure." Appeal Br. 18.

"By using the term 'consisting essentially of,' the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention." *PPG Indus. v. Guardian Indus. Corp*, 156 F.3d 1351, 1354 (Fed. Cir. 1998). Here, we agree with Appellant that the rejection of claims 13 and 16 should be reversed. In Burger, retinol is the active agent and Brahmanol® is combined with retinol to "potentiate the

action of retinol by increasing the amount of retinol available for conversion to retinoic acid." Burger 1:15–20, 1:61–63. Thus, retinol materially affects the basic and novel property of Brahmanol, because retinol is a second active agent that affects wound healing. *See*, *e.g.*, Spec. ¶ 21 ("[T]he final drug formulation (i.e. active ingredient plus pharmaceutically reliable carrier, and optionally additives). . ."). We conclude, therefore, that the "consisting essentially of" transition phrase of claims 13 and 16 excludes retinol from use in the claimed method.

In summary, we conclude that the rejection of claims 4–7, 12, 14, and 15 under 35 U.S.C. § 103(a) based on Burger and Elson is supported by a preponderance of the evidence, and we therefore affirm it. The rejection of claims 13 and 16 is not supported by a preponderance of the evidence, and we reverse it as to those claims.

DECISION SUMMARY

In summary:

Claims	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
Rejected				
4-7, 12-16	103	Burger, Elson	4–7, 12,	13, 16
			14, 15	

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED-IN-PART